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DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 4

RIN 2900-AN75

Schedule for Rating Disabilities; AL Amyloidosis (Primary Amyloidosis)

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its Schedule for Rating Disabilities by updating the schedule of ratings for the hemic and lymphatic systems to include AL amyloidosis. This regulatory action is necessary to add AL amyloidosis as one of the disease conditions and establish criteria for disability evaluation to fully implement the decision by the Secretary of Veterans Affairs to grant presumptive service connection based on herbicide exposure for this disease. The intended effects are to provide consistency in disability ratings and to ease tracking of AL amyloidosis for statistical analysis.

DATES: <u>Effective Date</u>: This final rule is effective [Insert date 30 days after date of publication in the FEDERAL REGISTER].

Applicability Date: This final rule applies to an application for benefits that:

 Is received by VA on or after [Insert 30 days after date of publication in the FEDERAL REGISTER];

- Was received by VA before [Insert 30 days after date of publication in the
 FEDERAL REGISTER] but has not been decided by a VA regional office as
 of that date;
- Is appealed to the Board of Veterans' Appeals on or after [Insert 30 days after date of publication in the FEDERAL REGISTER];
- Was appealed to the Board before [Insert 30 days after date of publication in the FEDERAL REGISTER] but has not been decided by the Board as of that date; or
- Is pending before VA on or after [Insert 30 days after date of publication in the FEDERAL REGISTER] because the Court of Appeals for Veterans
 Claims vacated a Board decision on the application and remanded it for readjudication.

FOR FURTHER INFORMATION CONTACT: Thomas J. Kniffen, Chief, Regulations Staff (211D), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 461-9700. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On October 22, 2010, VA published in the Federal Register (75 FR 65279) a proposed rule that would add AL amyloidosis to VA's Schedule for Rating Disabilities to update the schedule of ratings for the hemic and lymphatic systems, 38 CFR 4.117, by creating diagnostic code 7717. The schedule previously did not contain a diagnostic code for AL amyloidosis. As

an unlisted condition, it has been rated by analogy to non-Hodgkin's lymphoma using the "built-up" diagnostic code 7799–7715. However, AL amyloidosis requires a set of evaluation criteria with a unique diagnostic code, to serve as a basis for disability rating, because the condition is not part of the group of diseases under the non-Hodgkin's lymphoma classification, but, rather, a disorder of the bone marrow characterized by the accumulation and deposition of abnormal, insoluble proteins called light chain amyloid proteins in any organ of the body, interfering with the structure and function of the organ. Additionally, adding the diagnostic code would establish criteria for disability evaluation to fully implement the decision by the Secretary of Veterans Affairs to grant presumptive service connection based on herbicide exposure for this disease. A final rule regarding that decision was published in the Federal Register at 74 FR 21258, which amended 38 CFR 3.309(e) by adding AL amyloidosis to the list of diseases associated with exposure to certain herbicide agents. For these reasons, VA proposed a regulation that would amend VA's Schedule of Rating Disabilities by adding rating guidance and a diagnostic code specifically for AL amyloidosis.

VA proposed diagnostic code 7717 for AL amyloidosis because it was the first available diagnostic code in the Hemic and Lymphatic Systems listed in § 4.117. VA proposed to assign a 100 percent rating because the disease is incurable and progressive, generally causing death in a few years. Providing a 100-percent evaluation in all cases would obviate the need to repeatedly reassess and reevaluate veterans with AL amyloidosis over a short period of time. Because of the poor prognosis, no follow-up examination will be required for re-evaluation

of this disability rating. VA also proposed to refer to AL amyloidosis in diagnostic code 7717 as "primary amyloidosis," which is another common name for the same disease. VA also proposed to amend 38 CFR Part 4, Appendices A, B, and C to reflect the proposed addition of diagnostic code 7717 for AL amyloidosis to the rating schedule.

Comment in Response to Proposed Rule

A 60-day comment period ended December 21, 2010, and we received one comment from a member of the general public. The comment expressed support for the rule. We are not making any changes in the final rule based on this supportive comment.

As no further comments were received, we thus are making no changes to the proposed rule. Therefore, based on the rationale set forth in the proposed rule and this document, we are adopting the provisions of the proposed rule as a final rule with no changes.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any given year. This rule will have no such effect on State, local, and tribal governments, or on the private sector.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a "significant regulatory action," which requires review by the Office of Management and Budget (OMB), as "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined not to be a significant regulatory action under Executive Order 12866.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. The rule could affect only VA beneficiaries and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

<u>Catalog of Federal Domestic Assistance</u>

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are as follows: 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on February 2, 2012, for publication.

List of Subjects in 38 CFR part 4

Disability benefits, Pensions, Veterans.

Dated: February 3, 2012

Robert C. McFetridge,
Director of Regulation Policy and Management,
Office of the General Counsel,
Department of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 4 is amended as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

Subpart B-Disability Ratings

§ 4.117 [Amended]

2. In § 4.117, add diagnostic code 7717, immediately following the note at the end of diagnostic code 7716, to read as follows:

§ 4.117 Schedule of ratings—hemic and lymphatic systems.

					Rating
4	*	*	*	*	
7717 A	L amylo	oidosis	(primar	y amyloido	osis)100

3. In Appendix A to Part 4, under Sec. 4.117, add diagnostic code 7717 in numerical order (following diagnostic code number 7716) to the table to read as follows:

APPENDIX A TO PART 4—TABLE OF AMENDMENTS AND EFFECTIVE DATES SINCE 1946

Sec.	Diagnostic Code No.	
* * * * 4.117 * * * *	* * *	
* * * *	7717	Added [Insert date 30 days after date of publication of the final rule in the FEDERAL REGISTER].

4. In Appendix B to Part 4 add diagnostic code 7717 to the table in numerical order (following the entry for diagnostic code number 7716) and its disability entry "AL amyloidosis (primary amyloidosis)" to read as follows:

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES

Diagnostic Code No.	
* * * * * * *	
THE	HEMIC AND LYMPHATIC SYSTEMS
* * * 7717 * * *	* * * * AL amyloidosis (primary amyloidosis). * * * *

5. Appendix C to Part 4 is amended by adding in alphabetical order (following "Agranulocytosis") a new entry "AL amyloidosis" and its diagnostic code number "7717" to read as follows:

APPENDIX C TO PART 4-ALPHABETICAL INDEX OF DISABILITIES

*
7717
*

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